

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Ronald W. MINK *et al.*) Group Art Unit: 1723
)
Application No.: 09/292,293) Examiner: D. Sorkin
)
Title: DEVICE FOR COLLECTION AND ASSAY)
OF ORAL FLUIDS)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Prior to the examination of the above-identified application on the merits, please amend the application as follows.

In the Claims:

Please add the following claims:

48. A method of detecting an analyte in oral fluid of a subject, said method comprising:
inserting an apparatus for collection and lateral flow chromatography of an oral fluid, the apparatus comprising:
a lateral flow chromatography strip including a receiving area;
a capillary matrix having a surface; and
a bite portion coupled to the capillary matrix and insertable between teeth of a subject to position the surface of the capillary matrix for receiving an oral fluid of the subject, the capillary matrix being in communication with the lateral flow chromatography strip to wick up and deliver the received oral fluid to the receiving area of the lateral flow chromatography strip,
into the oral cavity of said subject such that said bite portion is held between the teeth of said subject;

retaining said apparatus in said oral cavity until an oral fluid sample is collected; and
reading the presence or absence of said analyte from an indicator region on said apparatus.

49. A method of detecting an analyte in oral fluid of a subject, said method comprising:
- inserting an apparatus for collection and lateral flow chromatography of an oral fluid, the apparatus comprising:
 - a lateral flow chromatography strip including a receiving area;
 - a bite portion insertable between the teeth of a subject; and
 - collection means coupled to the bite portion to contact an oral mucosa of the subject for receiving oral fluid of the subject, and in communication with the lateral flow chromatography strip for wicking up and delivering the received oral fluid to the receiving area of the lateral flow chromatography strip;
 - into the oral cavity of said subject such that said bite portion is held between the teeth of said subject;
 - retaining said apparatus in said oral cavity until an oral fluid sample is collected;
 - and
 - reading the presence or absence of said analyte from an indicator region on said apparatus.

REMARKS

Two claims have been added. Applicants respectfully submit that no new matter has been introduced by this Preliminary Amendment.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fees to our deposit Account 50-0310.

Respectfully submitted,
MORGAN, LEWIS & BOCKIUS LLP

By: Forchisha M. Davis
Forchisha M. Davis
Registration No. 48,371

Date: October 11, 2001

Customer No. 009629
Morgan, Lewis & Bockius LLP
1800 M Street, N.W.
Washington, D.C. 20036-5869
(202) 467-7000